

CLAIMS

1. A sampling device for obtaining samples of internal body substances in the digestive tract of a patient, said device having a shape of a swallowable capsule (2) which allows a sample of the body substance to enter the capsule through at least one inlet opening (18) which is opened in a predetermined position of the digestive tract following contact with the body substance to be collected,

characterised in that the capsule (2) comprises

a capsule wall (3) comprising said inlet opening (18), which initially is sealed and, when the patient has swallowed the capsule (2), is opened in said predetermined position following contact with the body substance to be collected,

an inner chamber (5), defined by said capsule wall (3) and disposed to preserve a vacuum or substantial underpressure when the inlet opening (18) is sealed, and

a blocking member (12) disposed in the inner chamber (5) adjacent to the inlet opening (18) in the capsule wall (3), said blocking member (12) being elastic and having a configuration, such that, when the inlet opening (18) has been opened following contact with said body substance, the blocking member (12) has a flow permitting configuration which admits a flow of body substance into the inner chamber (5) as long as there is a pressure difference between the inner chamber (5) and the external environment of the capsule (2) and a flow preventing configuration which blocks the inlet opening (18) from the inside of the chamber (5) when said pressure difference has been equalised by the flow of body substance into the capsule (2).

2. A sampling device according to claim 1, **characterised** in that the inlet opening (18) is sealed by a plug member (20) of a material that is dissolved following contact with said body substance.

3. A sampling device according to claim 1, **characterised** in that the blocking member (12) consists of an elastic, self-sealing membrane, which in said flow preventing configuration sealingly bears on the inside

of the capsule wall (3), such that an outflow of the body substance in the inner chamber (5) is prevented.

4. A sampling device according to claim 3, **characterised** in that the capsule (2) comprises two members, a cap member (4) and a body member (6), which are permanently joined to each other, and that said blocking member (12) is clamped in the capsule wall (3) between said cap member (4) and said body member (6).

5. A sampling device according to claim 4, **characterised** in that the blocking member (12) is substantially bulb-formed and has at least one laterally located aperture (16) for a through-flow of body substance into the inner chamber (5).

6. A sampling device according to claim 5, **characterised** in that a peripheral edge of the blocking member (12) is clamped between said cap member (4) and said body member (6).

7. A sampling device according to claim 2, **characterised** in that the plug member (20) consists of two or more layers of different materials and that each layer is dissolved in different positions in the digestive tract following contact with a specific body substance.

8. A sampling device according to claim 4, **characterised** in that a filter (10) is clamped between said cap member (4) and said body member (6) for filtrating the body substance that flows into the inner chamber (5).

9. A sampling device according to any of the preceding claims, **characterised** in that protrusions (30) are disposed externally on the capsule (2) circumferentially of the inlet opening (18), thereby forming inlet grooves (32) between the protrusions (30) for securing a free flow of body substance to the inlet opening (18).

10. A sampling method for obtaining samples of internal body substances in the digestive tract of a patient, wherein a capsule (2) is swallowed by the patient and the capsule (2) is opened in a predetermined position of the digestive tract following contact with the body substance to be collected,

characterised in that the body substance is aspirated into the capsule (2) by the force of a vacuum or substantial underpressure inside the capsule and that the body substance is blocked in the capsule (2) by an elastic, self-sealing blocking member (12) disposed inside
5 the capsule (2).

11. A sampling method according to claim 10, **characterised** in that the capsule (2) is opened to collect a sample in that a plug member (20) in an inlet opening (18) in the capsule wall (3) is dissolved following contact with the body substance to be collected.

10 12. A sampling method according to the claim 11, **characterised** in that said self-sealing blocking member (12) is opened to collect a sample of said body fluid by the force of the vacuum or substantial underpressure in the capsule (2) when the plug member (20) has been dissolved.

15 13. A sampling method according to claim 12, **characterised** in that said blocking member (12) is blocking the inlet opening (18) from the inside of the capsule (2) when the vacuum or substantial underpressure in the capsule has been equalised.

14. A method for producing a sampling device for obtaining samples of internal body substances in the digestive tract of a patient, said
20 device having a shape of a swallowable capsule (2) which allows a sample of the body substance to enter the capsule through at least one inlet opening (18) in the capsule wall (3) which is opened in a predetermined position of the digestive tracts following contact with the body
25 substance to be collected,

characterised in that the inlet opening (18) in the capsule wall (3) is sealed and/or that the capsule (2), which is made of two permanently joined members (4, 6), is permanently joined in a vacuum chamber (40) preserving a constant vacuum or substantial underpressure, such that
30 a vacuum or substantial underpressure is formed in an inner chamber (5) of the capsule when the inlet opening is sealed and/or when the two members (4, 6) of the capsule are permanently joined together.

15. A method according to claim 14, **characterised** in that said two members (4, 6) of the capsule are injection-moulded and are permanently joined together, preferably by ultrasonic welding.

5 16. A method according to claim 15, **characterised** in that an blocking member (12) of the inlet opening (18) is injection-moulded and is mounted between the two members (4, 6) of the capsule prior to permanently joining the two members together.

17. A method according to any of claims 14 – 16, **characterised** in that the inlet opening (18) of the capsule is sealed off by a plug member
10 (20), preferably made of an organic glue, and that the two members (4, 6) are joined together in the vacuum chamber (40).

18. A method according to any of claims 14 – 16, **characterised** in that the two members (4, 6) of the capsule are permanently joined together and that the capsule (2) is sealed off in a vacuum chamber (40)
15 in that a plug member (20) is applied in the inlet opening (18).

19. A method according to claim 18, **characterised** in that applications means (44) for applying the plug member (20), preferably a nozzle, is inserted into and through the inlet opening (18) in the capsule wall (3), that the application means (44) forces the blocking member
20 (12) to open, and that the application means (44) is withdrawn into the inlet opening (18) and the plug member (20), preferably of an organic glue, is applied in the opening (18) by said application means (44).